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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,964

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EXAMINER

MCMILLIAN, KARA RENITA

ART UNIT

PAPER NUMBER

1627

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/614,964	<b>Applicant(s)</b> DELUCA ET AL.	
	<b>Examiner</b> KARA R. MCMILLIAN	<b>Art Unit</b> 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 23-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-39 are pending.

#### ***Response to Amendment/Arguments***

No amendments to the claims were made. Claims 1-21 and 23-39 were previously withdrawn. Claim 22 is presented for examination

Applicant's arguments filed October 21, 2009 have been fully considered but they are not persuasive. Applicants argue that while it is true that the compound of instant claim 22 is encompassed by a combination of claims 1 and 8 of Deluca et al., the compound of present claim 22 is not specifically disclosed in Deluca et al. Applicants further argue that it is necessary to select various substituents from a list of several possibilities in order to arrive at Applicant's claimed compound. Thus, Applicants argue that a combination of claims 1 and 8 of Deluca et al. encompasses a vast number of compounds, and clearly encompasses a number which is significantly greater than the 20 compounds set forth in the case of *In re Petering*. These arguments are found not persuasive since it is clear, as Applicants have pointed out, that the combination of claims 1 and 8 of Deluca et al. teach Applicants claimed compound as long as Y<sub>1</sub>, Y<sub>2</sub>, R<sub>6</sub> and R<sub>8</sub> are all hydrogen. It is clear from the disclosure of Deluca et al. that hydrogen is the preferred substituent of Y<sub>1</sub>, Y<sub>2</sub>, R<sub>6</sub> and R<sub>8</sub> since in both Schemes I and II in columns 21-26 of Deluca et al. the end products are exemplified with hydrogen being the substituent of Y<sub>1</sub>, Y<sub>2</sub>, R<sub>6</sub> and R<sub>8</sub>.

Applicants further argue that the side chain of claim 8 is not a preferred embodiment since nowhere in the description of Deluca et al. does it state that the side chain defined by claim 8 is a “preferred” side chain. This argument is found not persuasive as it is clear from Deluca et al. that said side chain is preferred as it is specifically claimed in claim 8 of Deluca et al.

For reasons of record and for the reasons presented above, the previous rejection under 35 USC 102 is hereby maintained and reproduced below. This action is made FINAL.

### ***Claim Rejections - 35 USC § 102***

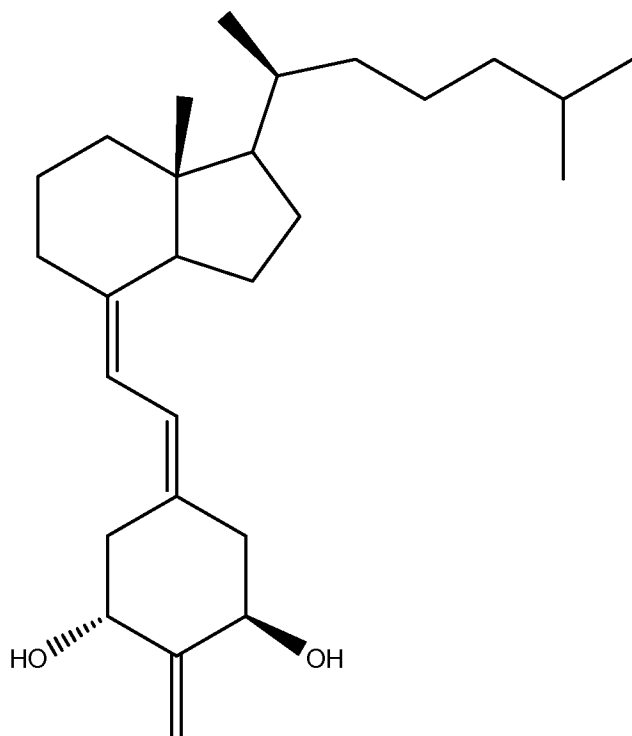
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

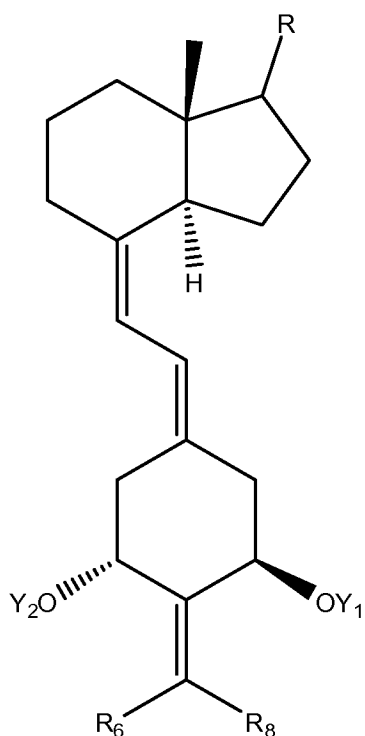
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Deluca et al. U.S. Patent No. 5,843,928 (provided on IDS).

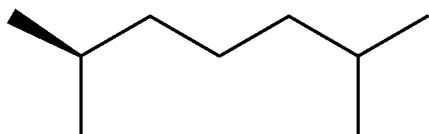
Claim 22 of the instant application claims the compound (20S)-1 $\alpha$ -hydroxy-2-methylene-19-nor-vitamin D<sub>3</sub> having the formula:



Deluca et al. claim a novel class of vitamin D related compounds, namely, the 2-alkylidene-19-nor-vitamin D derivatives (see abstract). Claim 1 of Deluca et al. claims a compound having the formula:



where Y<sub>1</sub> and Y<sub>2</sub> are selected from the group consisting of hydrogen and a hydroxyl-protecting group and R<sub>6</sub> and R<sub>8</sub> are selected from hydrogen, alkyl, hydroxyalkyl and fluoroalkyl, or when taken together represent the group —(CH<sub>2</sub>)<sub>x</sub>, where x is an integer from 2 to 5. Claim 8 of Deluca et al. claims the compound of claim 1 where R is a side chain of the formula:



Applicant's claimed compound is exemplified in claim 8 of Deluca et al. when Y<sub>1</sub>, Y<sub>2</sub>, R<sub>6</sub> and R<sub>8</sub> are all hydrogen. The compound of instant claim 22 is anticipated since an ordinary skilled artisan would be able to clearly envisage Applicant's claimed

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compound from Deluca et al. since and the  $Y_1$ ,  $Y_2$ ,  $R_6$  and  $R_8$  genus are limited, thus very few combinations can be obtained. Please note that if one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be “at once envisaged.” One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

### ***Conclusions***

Claim 22 is rejected. Claims 1-21 and 23-39 are withdrawn. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is (571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara R. McMillian/  
Examiner, Art Unit 1627

KRM

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627